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# Fax Cover Sheet

Date: 29 Jun 2004

To: Mary Kay	From: Patricia A. Duffy
Application/Control Number: 10/076,634	Art Unit: 1645
Fax No.: 202-408-4400	Phone No.: 571-272-0855
Voice No.:	Return Fax No.: (703) 872-9306
Re: 10/076,634	CC:
<input checked="" type="checkbox"/> Urgent <input type="checkbox"/> For Review <input type="checkbox"/> For Comment <input type="checkbox"/> For Reply <input type="checkbox"/> Per Your Request	

Comments:

To: Mary Kay,

Attached is a copy of missing page 14 of the office action for the above recited Application number. If I can be of further help, please call me.

Thank you,

*Patricia A. Duffy*  
Exr. Patricia Duffy

Number of pages 2 including this page

## STATEMENT OF CONFIDENTIALITY

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UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER	FILING DATE <u>10/07/03</u>	FIRST NAMED APPLICANT	ATTORNEY DOCKETT NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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002904

DATE MAILED:

### EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) Mary Kay (3) \_\_\_\_\_

(2) Patricia Duffy (4) \_\_\_\_\_

Date of interview 6/29/04

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☐ No. If yes, brief description: \_\_\_\_\_

Agreement ☐ was reached with respect to some or all of the claims in question. ☐ was not reached.

Claims discussed: \_\_\_\_\_

Identification of prior art discussed: \_\_\_\_\_

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: MS Kay indicated

that pg 14 was missing from the last office action of record. The examiner faxed to  
MS Kay missing page 4 to 202-408-4400.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ 1. It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph below has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ 2. Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the substance of the interview unless box 1 above is also checked.

Patricia Duffy  
Examiner's Signature

As to claim 21, the claim is uninterpretable, the claim recites obtaining the fusion protein by the process of claim 14 and releasing insulin therefrom, however, the fusion protein of claim 14 is not directed to an insulin fusion protein.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "signal sequence" in claims 2-5, is used by the claim to mean "a nucleic acid sequence that increases yield", while the accepted meaning is "a peptide present on proteins that are destined with to be secreted or the be membrane components. It is usually at the N terminus and normally absent from the mature protein. Normally refers to the sequence (ca 20 amino acids) that interact with signal recognition particle and directs the ribosome to the endoplasmic reticulum where co translational insertion takes place." The term is indefinite because the specification does not clearly redefine the term and the term does not provide for the property of increasing yield.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 9-15, 17, 22 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dawson et al, WO 91/09125 published 27 June 1991.